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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,922	11/24/2003	Markus Pompejus	BGI-132CPCN	5830

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EXAMINER	
ZARA, JANE J	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 06/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/721,922	POMPEJUS ET AL.	
	Examiner	Art Unit	
	Jane Zara	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 January 1938*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-38* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 1-38 are pending in the instant application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-17, 25-34 and 36-38, drawn to compositions and methods comprising nucleic acids, classifiable in class 435, subclass 69.1.

II. Claims 18-24, drawn to polypeptides, classifiable in class 530, subclass 300.

III. Claim 35, drawn to a method of diagnosing the presence or activity of Corynebacterium *diphtheriae* in a subject, classified in class 435, subclass 6.

Applicants are additionally required to elect the following with the corresponding elected group:

i. a single nucleotide sequence from Groups I and III;

ii. a single polypeptide sequence from Group II.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the

different inventions are drawn to different methods that result in different biological properties, functions or products, and comprise different and distinct steps: methods of making a recombinant polypeptide (Group I method of diagnosing presence or activity of Corynebacterium *diphtheriae* in a subject (Group III). Each method involves either monitoring for a distinct function or biological effect, or involves different and distinct methods steps and therefore each Group comprises different assay or active steps, each examining a different biological outcome. The searches required for proper examination of each distinct group are not coextensive, although some searches may be overlapping.

Inventions of Groups I and II are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are biologically, chemically, structurally and functionally different and distinct from each other and thus one does not render the other obvious. The nucleic acids of Group I could be used for other methods, including for the generation of recombinant polypeptides, cellular expression studies or competitive binding assays. The polypeptides of Group II are not required for making Group I and vice versa (each Group can be synthesized chemically or isolated from cells.) For these reasons, the inventions of these different and distinct Groups are capable of supporting separate patents.

Furthermore, searching the inventions of Groups comprising all of these different molecules, and the methods comprising them together would impose a serious search

burden. In the instant case, the search of the distinct methods and compositions are not coextensive. There is a search burden also in the non-patent literature. Prior to the concomitant construction and utilization of the different compositions of interest there may be journal articles devoted solely to one Group that would not have described the compositions and methods of the other Group. Searching, therefore is not coextensive. As such, it would be burdensome to search the inventions of the different Groups together.

The different inventions drawn to each polynucleotide SEQ ID NO. or polypeptide are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different compositions and methods comprising them are biologically, structurally and functionally different and distinct from each other. The methods involving the use of a distinct poly or oligonucleotide utilize a different and distinct composition, and so utilizes distinct methods steps from each other. For these reasons, the inventions of these different Groups are patentably distinct.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods comprising administration of different nucleic acid poly or oligonucleotides are unrelated as they comprise distinct steps and utilize different nucleic acid constructs which demonstrates that each method has a different mode of operation. The methodology

and materials necessary for each of these distinct methods differ significantly, and each Group constitutes a biologically, chemically and functionally distinct and different composition and method and therefore each involves a patentably distinct invention. Therefore, each method is divergent in materials and steps. For these reasons the inventions of these different Groups are patentably distinct.

Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the different nucleic acids and polypeptides, and their corresponding SEQ ID Nos. are subject to restriction. In the instant case, one independent and distinct nucleic acids and polypeptides will be examined in a single application without restriction. Those sequences or structures which are patentably indistinct from the sequence or region selected by the applicant will also be examined. Each of these nucleic acids and polypeptides is considered to be structurally independent, because each is represented by a unique sequence. Furthermore, a search of all the sequences claimed presents an undue burden on the Patent and Trademark Office to search and examine. In view of the foregoing, applicants are required to elect up to **one (1)** SEQ ID No.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. 1.6(d)). The official fax telephone number for the Group is **571-273-8300**. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(571) 272-0765.** If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on (571) 272-4517. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (571) 272-0564. Any inquiry of a general nature or relating to the status of

this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jane Zara
5-31-06

TC 1600

JANE ZARA, PH.D.
PRIMARY EXAMINER